



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2014-N-1168]

Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives; Public Hearing;
Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing that will provide an overview of the current status of regulatory science initiatives for generic drugs and an opportunity for public input on research priorities in this area. FDA is seeking this input from a variety of stakeholders--industry, academia, patient advocates, professional societies, and other interested parties--as it fulfills its commitment under the Generic Drug User Fee Amendments of 2012 (GDUFA) to develop an annual list of regulatory science initiatives specific to generic drugs. FDA will take the information it obtains from the public hearing into account in developing the fiscal year (FY) 2016 Regulatory Science Plan.

DATES: The public hearing will be held on June 5, 2015, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early depending on the level of public participation.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD

20993-0002. Entrance for the public hearing participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Registration and Requests for Oral Presentations: The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend (either in person or by Webcast (see Streaming Webcast of the Public Hearing)) and/or present at the hearing, please register for the hearing and/or make a request for oral presentations or comments by email to GDUFARegulatoryScience@fda.hhs.gov by May 15, 2015. The email should contain complete contact information for each attendee (i.e., name, title, affiliation, address, email address, telephone number, and priority number(s)). Those without email access can register by contacting Thushi Amini by May 15, 2015 (see For Further Information Contact).

FDA will try to accommodate all persons who wish to make a presentation. Individuals wishing to present should identify the number of the topic, or topics, they wish to address (see section V under Supplementary Information). This will help FDA organize the presentations. FDA will notify registered presenters of their scheduled presentation times. The time allotted for each presentation will depend on the number of individuals who wish to speak. Once FDA notifies registered presenters of their scheduled times, they are encouraged to submit an electronic copy of their presentation to GDUFARegulatoryScience@fda.hhs.gov on or before May 22, 2015. Persons registered to make an oral presentation are encouraged to arrive at the hearing room early and check in at the onsite registration table to confirm their designated

presentation time. An agenda for the hearing and other background materials will be made available 5 days before the hearing at <http://www.fda.gov/GDUFARegScience>.

If you need special accommodations because of a disability, please contact Thushi Amini (see For Further Information Contact) at least 7 days before the hearing.

Streaming Webcast of the Public Hearing: For those unable to attend in person, FDA will provide a live Webcast of the hearing. To join the hearing via the Webcast, please go to <https://collaboration.fda.gov/gdufa2012/>.

Comments: Regardless of attendance at the public hearing, interested persons may submit either electronic comments to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), 5600 Fishers Lane, rm. 1061, Rockville, MD 20857. The deadline for submitting comments to the docket is June 26, 2015. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> or <http://www.fda.gov/GDUFARegScience>. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thushi Amini, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 4728,

Silver Spring, MD 20993; 240-402-7958, email: Thushi.Amini@fda.hhs.gov; or Robert Lionberger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 4722, Silver Spring, MD 20993, 240-402-7957, email: Robert.Lionberger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, Congress passed GDUFA (Title III of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144)). GDUFA is designed to enhance public access to safe, high-quality generic drugs and reduce costs to industry. To support this goal, FDA agreed in the GDUFA commitment letter to work with industry and interested stakeholders on identifying regulatory science research priorities specific to generic drugs for each fiscal year covered by GDUFA. The commitment letter outlines FDA's performance goals and procedures under the GDUFA program for the years 2012-2017. The commitment letter can be found at <http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf>.

II. FY 2013 Regulatory Science Priorities

The FY 2013 regulatory science research priorities list was developed by FDA and industry and included in the GDUFA commitment letter. To implement the FY 2013 priorities list, the Office of Generic Drugs awarded \$17 million in external contracts and grants to initiate new research studies during FY 2013. Four million dollars were allocated to support internal research related to generic drugs. This includes rapid response capabilities through equipment for FDA labs and support for laboratory research fellows at FDA, as well as research fellows to work on data analysis and coordination of internal activities with external grants and contracts.

III. FY 2014 Regulatory Science Priorities

On June 21, 2013, the Office of Generic Drugs held a public hearing to gain input in developing the FY 2014 regulatory science priorities list. This list was prepared based on internal Center for Drug Evaluation and Research discussions, comments received from this public hearing, and comments submitted to the public docket. The FY 2014 priorities list can be found at <http://www.fda.gov/GDUFARegScience>. To implement the FY 2014 priorities list, the Office of Generic Drugs awarded \$17 million in external contracts and grants to initiate new research studies during FY 2014. A list of FY 2014 awarded studies can be found at <http://www.fda.gov/GDUFARegScience>.

IV. FY 2015 Regulatory Science Priorities

On May 16, 2014, the Office of Generic Drugs held a public meeting to allow public input in developing the FY 2015 regulatory science priorities list. The FY 2015 Regulatory Science Priorities are as follows:

1. Postmarket Evaluation of Generic Drugs
2. Equivalence of Complex Products
3. Equivalence of Locally Acting Products
4. Therapeutic Equivalence Evaluation and Standards
5. Computational and Analytical Tools

For more information on these topic areas, please visit www.fda.gov/GDUFARegScience. The Office of Generic Drugs is currently developing research studies to support the FY 2015 priorities list. Funding opportunities for collaborations will be posted in March 2015 at www.fda.gov/GDUFARegScience.

V. Purpose and Scope of the June 5, 2015, Public Hearing

The purpose of the June public hearing is to obtain input from industry and other interested stakeholders on the identification of regulatory science priorities for FY 2016. To help fulfill FDA's mission, FDA is particularly interested in receiving input on the following topics:

1. Opportunities for scientific or technical advancements that would help to overcome specific barriers for industry that currently limit the availability of generic drug products.
2. Innovative approaches to preapproval development of generic drugs, including new methodologies for design and conduct of in vitro, ex vivo, and clinical studies and identification of scientifically robust strategies for demonstration of bioequivalence for various product classes.
3. Innovations in scientific approaches to evaluating the therapeutic equivalence of generic drug products through later stages of their lifecycle following initial approval.
4. Identification of high-impact public health issues involving generic drugs that can be addressed by the prioritized allocation of FY 2016 funding for regulatory science research.
5. Identification of specific issues related to generic drug products where scientific recommendations and/or clarifications are needed in developing and/or revising FDA's guidance for industry.
6. Strategies for enhancing quality and equivalence risk management during generic drug product development, during regulatory review, and/or throughout the drug product's lifecycle following initial approval.

FDA will consider all comments made at this hearing or received through the docket (see [Comments](#) under Addresses) as it develops its FY 2016 GDUFA Regulatory Science Plan.

Additional information concerning GDUFA, including the text of the law and the commitment letter, can be found at <http://www.fda.gov/gdufa>.

VI. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with 21 CFR part 15. The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the Center for Drug Evaluation and Research. Under § 15.30(f) (21 CFR 15.30), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may pose questions; they may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under § 10.205 (21 CFR 10.205), representatives of the media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see Transcripts under Addresses). To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this document acts as a waiver of those provisions as specified in § 15.30(h).

Dated: February 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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